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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/417,175	10/11/1999	NANCY J. HARPER	PC10139AMAG	7073

7590 02/26/2003

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EXAMINER
OH, TAYLOR V

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/417,175	HARPER ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-12 and 14-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-12 and 14-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Non-Final Rejection

I. The request filed on 1/28/2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/417,175 is acceptable and a CPA has been established. An action on the CPA follows.

The Status of Claims :

Claims 1, 7-12, and 14-19 are pending.

Claims 1, 7-12, and 14-19 have been rejected.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

II. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

III. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

IV. Claims 1, 7-12, and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doogan et al (U.S. 4,962,128) in view of Howard et al (U.S. 5,597,826) and Johnson (EP0768083).

Doogan et al discloses a pharmaceutical composition containing sertraline hydrochloride (see col. 1, line 68) with a dose from 25 mg to 200 mg for treating anxiety-related disorders (see col. 2, lines 20-23); in addition, oral pharmaceutical formulations can be flavored by means of various agents ; the composition contains sertraline or its

pharmaceutically acceptable salt, flavoring agents, and diluents such as ethanol, propylene glycol, and glycerin (see from col. 2 line 65 to col. 3, line 2).

However, Doogan et al differs from the instant invention in that 8 to 20 % ethanol is in glycerin, the flavoring agent is menthol, the preservative is butylhydroxytoluene, and each ml of the concentrate contains 151 mg of ethanol, 0.5 mg of menthol, 0.1 mg of butylhydroxytoluene, and 1011 mg of glycerin, and pharmacologically acceptable anions include methanesulfonate.

Howard et al discloses a pharmaceutical composition containing sertraline hydrochloride (see col. 20, line 31) with a dose from 0.1 mg to 200 mg (see col. 24, lines 7-8), suspending agents, non-aqueous vehicles such as ethyl alcohol, and preservatives (see col. 22, lines 51-56); in addition, oral pharmaceutical formulations can be flavored by means of various agents (see col. 23, lines 56-58). Also, the reference indicates that pharmacologically acceptable anions include methanesulfonate (see col. 20, lines 60-61).

Concerning the claimed range of ethanol in glycerin, the reference is silent. However, Johnson teaches the use of diluents such as ethanol and glycerin; furthermore, with respect to the limitation of a process with respect to ranges of pH, time and concentration does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. Concentration is well-understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control selectivity of a process. Therefore, the person having an ordinary skill in the art had desired to use an optimum range of ethanol in glycerin, it would have been obvious for the skillful artisan in the art to have obtained the claimed range of ethanol in glycerin by a routine

experimentation on the Johnson's ethanol and glycerin so as to form a proper liquid dose.

In reference to the flavoring agent being menthol, the reference is silent. However, Howard et al does teach that oral pharmaceutical formulations can be flavored by means of various agents (see col. 23, lines 56-58). Furthermore, it is well-known in the art that menthol has been used for masking unpleasant flavors. Therefore, the skillful artisan in the art had desired to develop a unique menthol taste in the oral pharmaceutical composition containing sertraline hydrochloride, it would have been obvious for the skillful artisan in the art to have selected the menthol flavor as the masking agent for the product.

With respect to each ml of the concentrate contained 151 mg of ethanol, 0.5 mg of menthol, 0.1 mg of butylhydroxytoluene, and 1011 mg of glycerin, the references are silent. However, the pharmaceutical oral composition can contain various excipients with varied concentrations so as to meet special needs for the patients' use. Therefore, the composition of various known excipients do not have any patentable weight in the instant invention in the absence of unexpected results.

Doogan et al does disclose the pharmaceutical composition containing sertraline hydrochloride (see col. 1, line 68) with a dose from 25 mg to 200 mg for treating anxiety-related disorders (see col. 2, lines 20-23); in addition, oral pharmaceutical formulations can be flavored by means of various agents ; the composition contains sertraline or its pharmaceutically acceptable salt, flavoring agents, and diluents such as ethanol, propylene glycol, and glycerin (see from col. 2 line 65 to col. 3, line 2). If elixirs are desired for oral administration , the sertraline may be combined with various flavoring agents (see from col. 2 lines 63-67).

Howard et al discloses expressly the pharmaceutical composition containing sertraline hydrochloride (see col. 20, line 31) with a dose from 0.1 mg to 200 mg (see col. 24, lines 7-8), suspending agents, non-aqueous vehicles such as ethyl alcohol, and preservatives (see col. 22, lines 51-56); in addition, oral pharmaceutical formulations can be flavored by means of various agents (see col. 23, lines 56-58). Also, the reference indicates that pharmacologically acceptable anions include methanesulfonate (see col. 20, lines 60-61). Both are definitively dealt with the pharmaceutical composition containing sertraline hydrochloride with an overlapping dose; both do describe that the pharmaceutical composition containing sertraline hydrochloride may be combined with various pharmaceutically acceptable inert carrier in the form of syrups and solutions. Therefore, if the skillful artisan in the art had desired to develop the product containing non-aqueous liquid concentrate compositions containing sertraline and methanesulfonate as pharmacologically acceptable anions, it would have been obvious to the skillful artisan in the art to have motivated to use Howard et al 's methanesulfonate into the Doogan et al pharmaceutical composition containing sertraline hydrochloride because, for oral administration, both do indicate that non-aqueous vehicles can be incorporated in the liquid preparations containing sertraline .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 703-305-0809. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2742 for regular communications and 703-305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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February 19, 2003

Alan L. Rotman

ALAN L. ROTMAN
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TECHNOLOGY CENTER 1600